

SEP 18 1998

General Information

Classification	Class II
Trade Name	FlexScope™ Fiber Optic Endoscope
Submitter	MatRix Medical, Inc. 14055 Grand Avenue Suite D Burnsville, MN 55337 (612) 892-0822
Contact	Amjad Ahmad President

Predicate Devices

Endoscopes from:

- |                      |         |
|----------------------|---------|
| • Microvasive, Inc.  | K850393 |
| • Codman & Shurtleff | K871978 |

Device Description

The FlexScope™ is a flexible deflectable endoscope intended to allow physicians to visualize tissue in body cavities and through natural body orifices. The device is designed to be advanced to the site of interest through a cannula or trocar or may be used in an open procedure. The device will be available in various diameters.

The method of construction and materials used for these flexible fiber optic endoscopes are substantially equivalent to previous endoscope products.

Intended Use

The FlexScope is intended to be used for visualization of tissue in general surgical applications.

## Testing

All materials are biocompatible and are suitable for this application.

Physical testing of the product included: dimensional inspection, bond strength testing, optical clarity, and performance under simulated conditions. All testing of the product yielded acceptable results.

## Summary of Substantial Equivalence

The FlexScope family of endoscopes are constructed of the same or substantially equivalent materials as the predicate products. The sizes and configurations available are also equivalent.

The clinical indications for use are identical to the predicate devices.

Therefore, due to the similarity of materials to other endoscopes, the test results and the identical indications for use to other endoscopes, MatRix Medical believes these products do not raise any new safety or effectiveness issues.